

SJ-EXHIBIT 7

U.S. DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATIONNOTICE OF INSPECTION
OF CONTROLLED PREMISES

DEA USE ONLY

FILE NUMBER

NAME OF INDIVIDUAL <i>Joshua Dougherty</i>	TITLE <i>Pharm Supervisor</i>
NAME OF CONTROLLED PREMISES Giant Eagle RX Distribution Center	DEA REGISTRATION NO. RG0491047
NUMBER AND STREET 2500 Lovi Road	DATE <i>5/24/2017</i>
CITY AND STATE Freedom, PA	ZIP CODE 15042
	TIME (initial inspection) <i>10:45 AM</i>

STATEMENT OF RIGHTS

1. You have a constitutional right not to have an administrative inspection made without an administrative inspection warrant.
2. You have the right to refuse to consent to this inspection.
3. Anything of an incriminating nature which may be found may be seized and used against you in a criminal prosecution.
4. You shall be presented with a copy of this Notice of Inspection.
5. You may withdraw your consent at any time during the course of the inspection.

ACKNOWLEDGMENT AND CONSENT

I, *Joshua Dougherty*, have been advised of the above Statement of Rights
(Name)
by DEA DI Michael D. Kupchick, who
(Title and Name)

has identified himself/herself to me with his/her credentials and presented me with this Notice of Inspection containing a copy of sections 302(f) and 510(a), (b) and (c) of the Controlled Substances Act (21 U.S.C. 822(f) and 21 U.S.C. 880(a), (b) and (c)), printed hereon, * authorizing an inspection of the above-described controlled premises. I hereby acknowledge receipt of this Notice of Inspection. In

addition, I hereby certify that I am the

(President) (Manager) (Owner)

for the premises described in this Notice of Inspection; that I have read the foregoing and understand its contents; that I have authority to act in this matter and have signed this Notice of Inspection pursuant to my authority.

I understand what my rights are concerning inspection. No threats or promises have been made to me and no pressure of any kind has been used against me. I voluntarily give consent for inspection of these controlled premises.

(Signature)

(Date)

WITNESSES:

(signed)

(signed)

(date)

(date)

* See Reverse

FORM DEA-82 (11-01) Previous editions are obsolete

Enclosure
Case Number



Certificate of Registration

Certificate No. 3000009407

(A certificate starting with a number 4, 5 or 6 does not permit the possession or sale of controlled substances or prescription drugs.)

Drug & Device Registration

132 Kline Plaza
Suite A
Harrisburg, PA 17104
(717) 787-4779

Category:

Distributor (Prescription)

GIANT EAGLE RX DISTRIBUTION CENTER
2500 LOVI ROAD
FREEDOM, PA 15042

Enclosure
Case Number 0000009407

The above business is registered in the required category to conduct and maintain a facility in accordance with the provisions of the Controlled Substance, Drug, Device and Cosmetic Act #64, approved September 9, 1972.

Issuance Date: October 01, 2015

Expiration Date: The Last Day of October, 2017

Christine C. Filipovich, MSN, RN

Christine C. Filipovich, MSN, RN
Deputy Secretary for Quality Assurance



pennsylvania
DEPARTMENT OF HEALTH

Karen M. Murphy, PhD, RN

Karen M. Murphy, PhD, RN
Secretary of Health

NOTE: THIS CERTIFICATE MUST BE POSTED IN A CONSPICUOUS PLACE ON THE PREMISES.



Board of Pharmacy

CONTROLLED SUBSTANCE PERMIT

July 1, 2017 - June 30, 2018 - Date Issued: June 21, 2017

Giant Eagle Rx Distribution Center

2500 Lovi Road
Freedom, PA 15042

LICENSE # MI0001031

DEA # RG0491047

Schedule II Narcotic
Schedule II Non-Narcotic
Schedule III Narcotic
Schedule III Non-Narcotic
Schedule IV All
Schedule V All

Enclosure

Case Number



Board of Pharmacy

WHOLESALE DRUG DISTRIBUTOR PERMIT

July 1, 2017 - June 30, 2018 - Date Issued: March 22, 2017

Giant Eagle Rx Distribution Center

2500 Lovi Road
Freedom, PA 15042

LICENSE # WD0559761

DEA # RG0491047



State of Ohio

STATE BOARD OF PHARMACY

77 South High Street, 17th Floor; Columbus, Ohio 43215-6126 TEL: 614/466-4143 FAX: 614/752-4836 EML: licensing@pharmacy.ohio.gov

Be it known that the **WHOLESALE DISTRIBUTOR OF DANGEROUS DRUGS** named below is duly registered, and is entitled to distribute dangerous drugs at wholesale in the state of Ohio until the expiration date of June 30, 2018.

Identification Number: WHS.012587000-03

SIGN AND KEEP IN A READILY RETRIEVABLE LOCATION AT THIS ADDRESS

RESPONSIBLE PERSON:

ADAM ZAKIN

GIANT EAGLE RX DISTRIBUTION CENTER
2500 LOVI ROAD
FREEDOM, PA 15042

SIGNATURE OF RESPONSIBLE PERSON

Any change of responsible person must be reported within 10 days on a "Notification of Change of Responsible Person" form. Before change of name, address, or ownership, immediately notify the Licensing Department of the State Board of Pharmacy. (see below)

CLASS: Wholesaler/Manufacturer - Category Three
BUSINESS TYPE: FS - Full Service

(KEEP THIS SECTION FOR FUTURE REFERENCE)**General Information**

A **CHANGE** in business name, address, ownership (not officers-see next paragraph for officer changes), or category requires **RE-APPLICATION & FEE**. The new application and required fee shall be submitted within thirty (30) days of the change. In the event of an address change, **notify** the Board of Pharmacy **BEFORE** moving any dangerous drugs. [Sections 4729.51 and 4729.52, O.R.C.; Rule 4729-9-16, O.A.C.]. For more information go to: <http://www.pharmacy.ohio.gov/Licensing/WDDD.aspx>, and choose the appropriate application.

In accordance with paragraph (A)(7) of 4729-9-16 (OAC) (effective January 1, 2009), if a wholesale distributor is incorporated, a criminal records check is required every time there is a change in officers. Contact the board office for the fingerprint cards or you can go to <http://www.ohioattorneygeneral.gov/Business/Services-for-Business/Webcheck> to request fingerprint cards BIM-12-98 (BCI) and FD-258 (FBI)

New Officers: When adding new officers, submit a written notice to the Board including full name, title, date of birth and last four of social security number for each new officer.

Any change of responsible person must be reported within 10 days, on a "Notification of Change of Responsible Person" form. For more information go to: <http://www.pharmacy.ohio.gov/Licensing/WDDD.aspx>

Notify the Board of Pharmacy in writing **14 days prior to discontinuing business**, whether closing or selling. Written notice [Discontinuing Business form is available at the link below] and state license must be mailed (return receipt requested) or hand delivered to the Board office. [Section 4729.62 O.R.C.; Rule 4729-9-07, O.A.C.]

For more information go to: <http://www.pharmacy.ohio.gov/Licensing/WDDD.aspx>

Notify the Board of Pharmacy **of any new** facilities, work or storage areas to be constructed or utilized for dangerous drugs, **or any changes** in operation of the registrant **before** being used or implemented. [Rule 4729-9-16, O.A.C.]

All communications will be done through EMAIL- NOT MAILINGS. Please go to the following webpage to provide the email address that you wish to receive these communications: <https://pharmacy.ohio.gov/UpdateEmailAddress.aspx>

In order to enter your email address in the webpage mentioned above, you will need your login information, which is below.

User ID: 4445445

Password: 759315

Current Email on File: GERXLICENSES@GIANTEAGLE.COM

If you have problems or concerns, please feel free to contact the Board office utilizing the "CONTACT THE BOARD" selection along the left side of the website. Be sure to select "General Licensing Information" as your subject line.

Enclosure
Case Number

4



State of Ohio



STATE BOARD OF PHARMACY

77 South High Street, 17th Floor; Columbus, Ohio 43215-6126 TEL: 614/466-4143 FAX: 614/752-4836 EML: licensing@pharmacy.ohio.gov

Be it known that the DISTRIBUTOR OF CONTROLLED SUBSTANCES named below is duly registered, and is entitled to distribute controlled substances in the state of Ohio until the expiration date of June 30, 2018.

Identification Number: WCSW.2852

SIGN AND KEEP IN A READILY RETRIEVABLE LOCATION AT THIS ADDRESS

RESPONSIBLE PERSON:

ADAM ZAKIN

GIANT EAGLE RX DISTRIBUTION CENTER
2500 LOVI ROAD
FREEDOM, PA 15042

SIGNATURE OF RESPONSIBLE PERSON

Any change of responsible person must be reported within 10 days on a "Notification of Change of Responsible Person" form. Before change of name, address, or ownership, immediately notify the Licensing Department of the State Board of Pharmacy. (see below)

CLASS: Controlled Substance Wholesaler
BUSINESS TYPE: FS - Full Service

(KEEP THIS SECTION FOR FUTURE REFERENCE)

General Information

A **CHANGE** in business name, address, ownership (not officers-see next paragraph for officer changes), or category requires **RE-APPLICATION & FEE**. The new application and required fee shall be submitted within thirty (30) days of the change. In the event of an address change, **notify** the Board of Pharmacy **BEFORE** moving any dangerous drugs. [Sections 4729.51 and 4729.52, O.R.C.; Rule 4729-9-16, O.A.C.]. For more information go to: <http://www.pharmacy.ohio.gov/Licensing/WDDD.aspx>, and choose the appropriate application.

In accordance with paragraph (A)(7) of 4729-9-16 (OAC) (effective January 1, 2009), if a wholesale distributor is incorporated, a criminal records check is required every time there is a change in officers. Contact the board office for the fingerprint cards or you can go to <http://www.ohioattorneygeneral.gov/Business/Services-for-Business/Webcheck> to request fingerprint cards BIM-12-98 (BCI) and FD-258 (FBI)

New Officers: When adding new officers, submit a written notice to the Board including full name, title, date of birth and last four of social security number for each new officer.

Any change of responsible person must be reported within 10 days, on a "Notification of Change of Responsible Person" form. For more information go to: <http://www.pharmacy.ohio.gov/Licensing/WDDD.aspx>

Notify the Board of Pharmacy in writing 14 days prior to discontinuing business, whether closing or selling. Written notice [Discontinuing Business form is available at the link below] and state license must be mailed (return receipt requested) or hand delivered to the Board office. [Section 4729.62 O.R.C.; Rule 4729-9-07, O.A.C.]
For more information go to: <http://www.pharmacy.ohio.gov/Licensing/WDDD.aspx>

Notify the Board of Pharmacy of **any new** facilities, work or storage areas to be constructed or utilized for dangerous drugs, or **any changes** in operation of the registrant **before** being used or implemented. [Rule 4729-9-16, O.A.C.]

All communications will be done through EMAIL- NOT MAILINGS. Please go to the following webpage to provide the email address that you wish to receive these communications: <https://pharmacy.ohio.gov/UpdateEmailAddress.aspx>

In order to enter your email address in the webpage mentioned above, you will need your login information, which is below.

User ID: 4445445

Password: 759315

Current Email on File: GERXLICENSES@GIANTEAGLE.COM

If you have problems or concerns, please feel free to contact the Board office utilizing the "CONTACT THE BOARD" selection along the left side of the website. Be sure to select "General Licensing Information" as your subject line.

U.S. Department of Justice
Drug Enforcement Administration

REPORT OF INVESTIGATION

Page 1 of 19

1. Program Code	2. Cross File Related Files	3. File No. [REDACTED]	4. G-DEP Identifier [REDACTED]
5. By: Michael D Kupchick, DI At: Pittsburgh DO	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	6. File Title GIANT EAGLE RX DISTRIBUTION CENTER, Freedom PA	
7. <input checked="" type="checkbox"/> Closed <input checked="" type="checkbox"/> Requested Action Completed <input type="checkbox"/> Action Requested By:		8. Date Prepared 05-26-2017	
9. Other Officers: DI Rita Esquivel-Blatt			
10. Report Re: Case Closing and Cyclic Investigation, GIANT EAGLE RX DISTRIBUTION CENTER, RG0491047, 2500 Lovi Road, Freedom, PA 15042 [REDACTED]			

SYNOPSIS

On May 24, 2017, pursuant to the Pittsburgh District Office (PGE DO) cyclic workplan for FY 2018, Diversion Investigators (DI) Michael Kupchick and Rita Esquivel-Blatt conducted an on-site regulatory investigation of GIANT EAGLE RX DISTRIBUTION CENTER, a Division of GIANT EAGLE, INC., located at 2500 Lovi Road, Freedom, PA 15042.

GIANT EAGLE RX DISTRIBUTION CENTER) (DEA # RG0491047, expiration September 30, 2018, [REDACTED]) is registered with DEA as a distributor to handle controlled substances in schedules 2, 3, 3N, 4 and 5. The onsite portion of this investigation began and concluded on May 24th, 2017 and concluded on August 1, 2017.

This investigation revealed no discrepancies with respect to recordkeeping or security. The audit of controlled substances revealed a shortage of 1,000 Lorazepam 1mg tablets.

No further action is required. This case is closed.

11. Distribution: Division	12. Signature (Agent) /s/ Michael D Kupchick, DI	13. Date 05-26-2017
District	14. Approved (Name and Title) /s/ Lewis D Colosimo, Acting GS	15. Date 11-08-2017
Other [REDACTED]		

DEA Form - 6
(Jul. 1996)

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Drug Enforcement Administration

REPORT OF INVESTIGATION <i>(Continuation)</i>	1. File No. [REDACTED]	2. G-DEP Identifier [REDACTED]
	3. File Title GIANT EAGLE RX DISTRIBUTION CENTER, Freedom PA	
4. Page 2 of 19		
5. Program Code	6. Date Prepared 05-26-2017	

ENCLOSURES

1. DEA-82 - Notice of Inspection
2. PA Dept of Health Drug Distributorship/ Wholesaler Certificates
3. West VA Pharmacy Controlled Substance/ Drug Distributorship Permit
4. State of Ohio Pharmacy Drug Distributorship Certificates
5. DEA Biennial Inventory
6. Closing Inventory
7. Audit Computation Chart
8. GERXDC Inventory records
9. DEA 222 and DEAE222 Order Forms
10. GERXDC Purchase records
11. GERXDC Sales Records
12. ARCOS Reports
13. Floor Plan
14. CSOS instructions

DETAILS

1. BASIS OF INVESTIGATION

On May 24, 2017, pursuant to the Pittsburgh District Office (PGH DO) cyclic work plan for FY 2018, Diversion Investigators (DI) Michael Kupchick and Rita Esquivel-Blatt conducted an on-site regulatory investigation of GIANT EAGLE RX DISTRIBUTION CENTER, a Division of GIANT EAGLE, INC., located at 2500 Lovi Road, Freedom, PA 15042

GIANT EAGLE RX DISTRIBUTION CENTER INC. (DEA # RG0491047, expiration September 30, 2018, [REDACTED]) is registered with DEA as a distributor to handle controlled substances in schedules 2, 2N, 3, 3N, 4 and 5. The onsite portion of this investigation began on May 24, 2017 and concluded on August 1, 2017, with a meeting with management.

2. SUBJECT FIRM'S BACKGROUND

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REPORT OF INVESTIGATION <i>(Continuation)</i>	1. File No [REDACTED]	2. G-DEP Identifier [REDACTED]
	3. File Title GIANT EAGLE RX DISTRIBUTION CENTER, Freedom, PA	
4 Page 3 of 19		
5 Program Code	6 Date Prepared 05-26-2017	

GIANT EAGLE RX DISTRIBUTION CENTER, to be referred to as GERXDC, is located at 2500 Lovi Road, Freedom, PA 15042, distributes Scheduled II controlled substances to approximately 220 Giant Eagle supermarkets located in Pennsylvania, West Virginia, and Ohio. Giant Eagle pharmacies are the subject firm's sole customer base. GERXDC CENTER had \$157,000,000 dollars in sales during 2017, of which controlled substances accounted for less than one percent.

GERXDC was approved as a drug distributor on January 8, 2016 and issued DEA registration number RG0491047 under DEA file number [REDACTED]. This registration expires on September 30, 2018.

GERXDC is licensed with the Commonwealth of Pennsylvania, Department of Health, as a distributor of prescription medicine, Certificate Number 300C009407, which expires on October 31, 2017 (*ENCLOSURE #2*). GERXDC is licensed with the State of West Virginia, Board of Pharmacy as a wholesale drug distributor under license number WD0559761, which expires on June 30, 2018 (*ENCLOSURE #3*). HBC is licensed with the State of Ohio, Board of Pharmacy as a distributor of controlled substances under ID Number WHS.C12587000-CB. This registration expires on June 30, 2018 (*ENCLOSURE #4*).

3. PERSONS INTERVIEWED AND INDIVIDUAL RESPONSIBILITIES

On May 24, 2017, Investigators Kupchick and Esquivel-Blatt presented their credentials and a Notice of Inspection (DEA Form 82) (*ENCLOSURE #1*) to Joshua DOUGHERTY, GERXDC Pharmacy Supervisor, for the subject firm. DOUGHERTY read and signed the DEA Form 82, giving his consent for the inspection to proceed. DOUGHERTY stated that he is responsible for the subject firm's inventory operations, with respect to controlled substances. DOUGHERTY, provided all the necessary records and information required to conduct this investigation.

4. PRINCIPALS OF THE FIRM

Laura Karet, President and CEO
Mark J. Minnaugh, CFO

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REPORT OF INVESTIGATION <i>(Continuation)</i>	1. File No. [REDACTED]	2. G-DEP Identifier [REDACTED]
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4. Page 4 of 19	6. Date Prepared 05-26-2017	
5. Program Code		

John Lucot, COO
Adam Zakin, Sr. Director of Pharmacy Administration
George Chunderlik, Manager of Pharmacy Compliance

NADDIS queries on these individuals did not reveal any negative information.

5. SCOPE OF INVESTIGATION

The on-site portion of the investigation commenced on May 24, 2017, and concluded on August 1, 2017, with a meeting with management.

An accountability of Oxycodone 30 mg tablets (Schedule II, drug code 2100) Morphine Sulfate ER 20 mg tablets (Schedule II, drug code 2784) Buprenorphine/Naloxone 8-2 mg tablets (Schedule III, drug code 9064) Buprenorphine/Naloxone 2-0.5 mg tablets (Schedule III, drug code 9064), Buprenorphine 8mg tablets (Schedule III, drug code 9064), Lorazepam 1mg tablets (Schedule IV, drug code 2885), Diazepam 5 mg tablets (Schedule IV, drug code 2765), and Acetaminophen/Sodium Phosphate 120mg/12mg/5ml (Schedule V, was conducted for the period March 23, 2016 (BOB), through May 24, 2017 (BOB).

The results of this audit are listed below and documented on the attached computation chart (ENCLOSURE #7). This accountability audit revealed a shortage of 1,000 lorazepam 1mg tablets, 0.02%. According to Chunderlik, the bottle of 1000 lorazepam 1mg tablets, was placed in the morgue area of GERXDC. Chunderlik stated that the morgue area of GERXDC is where expired and or damaged controlled substances and all other pharmaceuticals are placed while awaiting transfer to a reverse distributor for destruction. (All figures are in number of bottles/containers)

HBC SERVICES

DEA # RH0389773

Initial Inventory Date:

BOB 03/23/2016

Closing Inventory Date:

COB 05/24/2017

DATE 12/2/2014

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REPORT OF INVESTIGATION <i>(Continuation)</i>		1. File No. [REDACTED]	2. G-DEP Identifier [REDACTED]
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5. Program Code			

Drug Name, Strength, Form	Initial Inventory	Received	Total Accountable For	Closing Inventory	Distributed/Transferred	Total Accounted For	Total Difference	% Difference
Oxycodone 30 mg tabs	87,300	465,600	552,900	39,800	513,100	552,900	0	0
Morphine Sulphate ER 20 mg	1,900	18,000	19,900	2,900	17,000	19,900	0	0
Buprenorphine/Naloxone 8-2 mg	11,370	84,240	95,610	0	95,610	95,610	0	0
Buprenorphine/Naloxone 2-05mg	0	3,600	3,600	2,130	1,470	3,600	0	0
Buprenorphine 8mg	6,180	40,320	46,500	1,050	45,450	46,599	0	0
Diazepam 5mg tablets	86,000	1,152,000	1,238,000	27,000	1,211,000	1,238,000	0	0
Lorazepam 1mg Tab	<u>154,000</u>	<u>3,348,000</u>	<u>3,502,000</u>	<u>43,000</u>	<u>3,458,000</u>	<u>3,501,000</u>	<u>-1000</u>	<u>-0.02%</u>
Acetaminaphene/Sodium Phosphate	0	56,760	56,760	8514	48,246	56,760	0	0

6. RECORDKEEPING

Biennial Inventory:

A biennial inventory, as required by Title 21 C.F.R. 1304.11 (c), was taken by the subject firm on March 21, 2017. (ENCLOSURE #5)

Initial Inventory:

The figures for the initial inventory portion of the audit were taken from the firm's "NDC Audit Item Inventory" report dated March 23, 2016. Among other internal data, this computer-generated report captures the date, drug name, strength, bottle size, and quantity on hand for each controlled substance. CHUNDERLIK provided these figures as factual for the purposes of the audit's initial inventory. These records were maintained in accordance with the requirements set forth in Title 21 C.F.R. 1304.11.

Closing Inventory:

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REPORT OF INVESTIGATION <i>(Continuation)</i>	1. File No. [REDACTED]	2. G-DEP Identifier [REDACTED]
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5. Program Code		

On May 24, 2017, Dis Kupchick and Esquivel-Blatt conducted a physical count, closing inventory, which was witnessed by TEYSSIER. (Enclosure #6) This physical count was compared against the subject firm's "Item Inquiry" report which is a daily control substance inventory report, sorted by item number associated with each separate controlled substance. Among other internal data, this computer-generated report captures the date, time, drug name, strength, bottle size, and quantity on hand for each controlled substance. These figures were compared against the actual physical count and no discrepancies were found. These records were maintained in accordance with the requirements set forth in Title 21 C.F.R. 1304.11.

Receiving/Purchasing Records:

GERXDC maintains electronic copies of DEA-222 Order Forms via CSOS. DTs Kupchick and Esquivel-Blatt reviewed CSOS Order Forms, which were completed in accordance with 21 C.F.R. 1305.13. The subject firm's purchase records are further documented via the original purchase invoices from the drug suppliers, which are physically maintained and entered into a computer database by drug item number. These figures are captured on the subject firm's "NDC Audit Item Inventory Detail" report, a computer-generated report which, among other internal data, captures a complete, daily perpetual inventory of purchases and distributions of a particular controlled substance by date range (ENCLOSURE #8). A random selection of several purchases were taken from the "NDC Audit Item Inventory Detail" report, and compared against the original source document/purchase invoices for accuracy. No discrepancies were noted. These records were maintained in accordance with the requirements set forth in Title 21 C.F.R. 1304.22(b).

It should be noted that although the subject firm's drug distribution warehouse has computerized access to the "NDC Audit Item Inventory Detail" report, in order to compare this report against the original source document/purchase invoices, the investigators had to travel to the subject firm's corporate headquarters located at the RIDC Industrial Park, 101 Kappa Drive, Bldg. III, Pittsburgh, PA 15238. All purchases are a function of a centralized purchasing unit base at the subject firm's corporate headquarters.

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(Jul. 1996)

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On August 1, 2017, the investigators reviewed these records with Chunderlik. No discrepancies were found.

It should be noted that the subject firm submitted a written request for authorization for central recordkeeping for the purchase records to be physically stored at its corporate headquarters during the cyclic investigation conducted in 2011 under file number [REDACTED]

CSOS

GERXDC began using CSOS in March 2015 to electronically order all of their CII controlled substances. According to CHUNDERLIK all CSOS orders must be submitted by only a pharmacist by 10:00 am with a limit of 1 order per store per day. When an order is received, the eDEA222 must be printed and completely filled out as to quantities received and signed by the pharmacist. CHUNDERLIK provided investigators with a copy of GERXDC CSOS procedures. (Enclosure 14)

Sales/Distribution Records:

Since GERXDC is a division of Giant Eagle Supermarkets, its sole customer base is 220 Giant Eagle pharmacies located throughout PA, W.VA, and OH. Sales are initiated at the store level and are computer-generated from the individual store via CSOS and transmitted to the subject firm on a daily basis. GERXDC maintains electronic copies of DEA-222 Order Forms via CSOS. DI's Kupchick and Esquivel-Blatt reviewed CSOS Order Forms, which were completed in accordance with 21 C.F.R. 1305.13. DI's Kupchick and Esquivel-Blatt also reviewed GERXDC internal "Item Invoice Report." These computer-generated invoices capture information such as pharmacy location, DEA number, date of distribution, drug, strength and quantity sold (ENCLOSURE #8). These distribution transactions document daily distributions, within a specified date range, of each particular controlled substance to all customers. These records were maintained in accordance with the requirements set forth in Title 21 C.F.R. 1304.22(b).

Damaged/Returned Items:

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(Jul. 1996)

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REPORT OF INVESTIGATION (Continuation)	1. File No. [REDACTED]	2. G-DEP Identifier [REDACTED]
	3. File Title GIANT EAGLE RX DISTRIBUTION CENTER, Freedom PA	
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5. Program Code		

There were no returned items noted during the audit period. The subject firm utilizes Capital Returns as its reverse distributor in order to destroy controlled substances. There were no destructions of controlled substances noted during the audit period.

7. ARCOS

Prior to conducting the onsite inspection, DI's Kupchick and Esquivel-Blatt reviewed an ARCOS print out of the pre-selected controlled substances to be audited. The information contained in ARCOS was utilized to verify purchase information supplied by the subject firm during the audit period. No discrepancies were noted. GERXDC is working with ARCOS to correct the 327 error records. According to the ARCOS unit, GERXDC is submitting the ARCOS reports in a timely manner but that ARCOS was/is experiencing problems with the ARCOS EDI upload facility.

8. SECURITY

GERXDC, located in an industrial park (Tri-County Commerce Park) in New Sewickley Township, occupies 13,515 square feet of a 210,000 square foot building constructed of poured reinforced concrete, steel, and brick. Other occupants of the building are limited to Giant Eagle entities such as the Giant Eagle Pharmacy (Central Fill, no walk-in business - DEA Number FG5586447), Giant Eagle fresh foods department, and Giant Eagle storage of health and beauty supplies. Operating hours for the GERXDC will be 5:00 a.m. to 12:30 a.m., Monday through Saturday. GERXDC maintains sufficient external lighting to identify delivery drivers and trucks, as well as to light areas that are under 24 hour video surveillance.

Access to the GERXDC is limited to identifiable employees who have direct, day-to-day functions within the GERXDC (i.e. receiving, replenishment, stocking, and selection). Key FOBs/badges are required to enter and exit the GERXDC. The Key FOBs/badges also allow GERXDC management to restrict unauthorized access into the GERSDX, and further limit access to the firm's cage and vault.

All employees with access to the firm's cage and vault and those involved

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in handling Schedule 2-5 controlled substances must undergo the required background checks associated with the following 21 CFR sites: 1301.76, 1301.90, 1301.92, and 1301.93.

The cage and vault will be locked when not in use. It will be permissible for the cage to be unlocked when it is in use as long as it is being monitored by an authorized member of the GERXDC operation's management team. Keys to unlock the cage and vault will be in the possession of the operation's management.

GERXDC has multiple video surveillance cameras in the cage/vault, providing adequate monitoring of any employee movement while in the cage/vault.

Any visitor to GERXDC must first sign the Visitor's Log upon entering the facility. A visitor's admittance into the facility is permitted only when the visitor is accompanied by a member of the GERXDC operation's management team. The visitor must be supervised at all times. At no time will a visitor be unsupervised while in the GERXDC production area where items, including controlled substances, are store, received, or distributed.

In the event of a power loss, the GERXDC has an industrial-grade backup generator to ensure continuing operations.

The firm's electronic security is monitored by Sonitrol Security Systems, Inc (Sonitrol). Kevin Householder of Sonitrol informed DI Kupchick that alarm signals are transmitted from GERXDC to Sonitrol through a static IP, with a cellular backup. Householder stated that both forms of transmission are under constant supervision so that any tampering would be immediately detected. During non-operating hours, if the GERXDC or cage/vault alarm is activated, Sonitrol will contact the local police department (New Sewickley Township Police Department), as well as the GERXDC warehouse call list, which includes GERXDC Loss Prevention personnel, to inform management of the alarm activation. After GERXDC management investigates the matter, they will contact Sonitrol to inform them of the result of their investigation.

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On May 24, 2017, investigators tested the cage and vault electronic security. This test revealed that an audible alarm could be heard throughout the GERXDC upon unauthorized entry to the cage and vault. The attached results of the test, provided by Sonitrol Security Systems, revealed the security was deemed operational.

CAGE SPECIFICATIONS

All Schedule 3-5 controlled substances handled by GERXDC are stored in a cage measuring 46'5" x 27'8" x 29'1" (height), with the cage walls constructed of #10 gauge steel fabric mounted on 2" diameter posts. The placement of the posts and the fence openings are compliant with 21 CFR Part 1301.72. An examination of the fencing bolts revealed they were welded/brazed as required by this CFR site. The cage's ceiling and entrance doors are constructed of similar material as the cage's walls. The cage is equipped with self-locking doors; all cage doors are equipped with contact switches. Motion sensors and cameras are strategically positioned to provide adequate coverage.

All elements of this cage appear to meet the requirement specified in 21 CFR 1301.72(b) (4).

VAULT SPECIFICATIONS

All Schedule 2 controlled substances handled by GERXDC are stored in a vault measuring 38'8" x 40'2" x 29'1" (height). The walls, floor, and ceiling are constructed of 8" of poured concrete reinforced with #4 rebar tied 6 inches on center. The vault is equipped with a self-closing, self-locking day gate. The vault door, weighing over 4,000 pounds, is a metal AR5 security vault door manufactured by Overly Door Company, serial number M-5-1054. The vault is equipped with a combination lock. Motion sensors and cameras are strategically positioned in the vault to provide adequate coverage.

RECEIVING

GERXDC primary suppliers of controlled substances will be MCKESSON DRUG.

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All controlled substances delivered to the GERXDC must enter the building through the receiving man-doors #1 and #2, where they will be identified at the point of entry, and transported (by authorized personnel) approximately 100 feet into a secure area within the GERXDC. An operations manager is responsible for making sure the delivery of controlled substances into the building is secure, and checks the bill of lading to ensure the correct purchase orders have been received. When the shipment has been inspected, the controlled substances are transported directly to the cage/vault area. Video monitoring records the entire travel path from the receiving dock to the cage/vault.

STORAGE

All controlled substances are store in a secure cage or vault fully described elsewhere in this report. As outlined in the attached "Inventory Control - Suspected Loss Policy" - all generic controlled substances are cycle counted two times per week, while name brand controlled substances are counted nightly after selection is completed. The attached policy details outline other inventory counts and controls performed at GERXDC.

Inventory discrepancies and reports of used, tampered, or opened products are reported to management for investigation. Management will determine if the loss is significant. Criteria for a significant loss can include, but are not limited to the following:

- Any loss of a controlled substances.
- Discrepancies of five(5) percent or greater of the expected on-hand quantity.
- Repeated discrepancies of the same product within a rolling thirty (30) day period.
- Dollar value losses that exceed five hundred dollars (\$500.00) per occurrence.

Significant losses will be reported to DEA upon discovery.

SHIPPING

Upon completion of product selection, completed totes are stacked onto

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outbound pallets and prepared for shipping. An authorized employee scans each tote label and attaches all tote labels that are on the pallet to a pallet license plate number. The tote count per pallet is then recorded and documentation is printed for shipping verification. Each outgoing shipment/s are inspected for identity of the drug product, and the container is inspected to ensure no damage has occurred. When the outbound carrier arrives at GERXDC, a manager or supervisor supervises the loading of the pallets. Outbound paperwork will be taken to the loading door, and the manager or supervisor and outbound driver verifies the count of totes on each pallet, as well as the number of pallets to be shipped. Pallets/totes are also inspected at this time for any sign of visual damage or tampering. The driver's and manager's signatures are written on the bill of lading indicating that the counts are correct. If the counts are not correct, the manager will investigate the matter. The Warehouse Operations Manager or GERXDC Supervisor performs and document random audits for outgoing shipments. Video surveillance monitoring will cover the path from the cage/vault to the loading door.

Prior to a delivery truck arriving or departing from the warehouse facility, exterior mounted video surveillance cameras are viewed at a terminal located in the pharmacy warehouse to ensure there are no unknown persons or vehicles near the facilities loading docks. When a delivery truck is backed into the loading dock platform there is a security device that shrouds the rear of the truck making it impossible to gain access to the pharmacy warehouse room from the building's exterior. Once the vehicle is locked in place, the supervisor closes the exterior door before allowing the driver to enter. The supervisor ensures the holding area is secure and then allows the driver into the holding area. Once the exterior door is closed behind the driver, the supervisor will release the holding area door to allow the driver inside the pharmacy warehouse.

The supervisor will then unlock the padlock that secures the grade-level garage door. If the delivery contains controlled substances, the supervisor unlocks the cage so the product can be taken directly into the protected area. The reconciliation takes place inside the cage by the receiver, but excludes the driver. If the driver arrives for pick up, the supervisor follows the same steps indicated for the receiving process before allowing the driver access inside.

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CHUNDERLIK informed DTs Kupchick and Esquivel-Blatt that the following individuals have routine access to GERXDCs controlled substance storage cage (ENCLOSURE #10):

Name	Social Security Number	Date of Birth
Joshua Dougherty	[REDACTED]	
Mat Hubert		
Jacob Teyssier		
Dave Hubsch		
Sarah Brianne Pappas		

A NADDIS check revealed no derogatory information on these individuals.

Talon Logistics, the exclusive private carrier for Giant Eagle, is the primary carrier for GERXDC. Other private carriers used by GERXDC are Prestige Delivery Systems and Aim Dedicated Logistics. As per 21 CFR 1301.74(e), the firm is responsible for selecting a common or contract carrier which provides adequate security to guard against in-transit losses. HBC has used all three carriers identified above. As noted in the Theft/Loss section of this report, a review of DEA's Theft/Loss database revealed HBC has filed only four DEA Form 106s (Report of Theft or Loss of Controlled Substances) since they were approved by DEA as a distributor in 2016: one loss was attributed to employee pilferage (his employment was terminated); three were described as in-transit losses. HBC appropriately documented on each of the forms security measures they took to prevent or limit future thefts/losses.

Customer Authentication

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To ensure that controlled substances are distributed only to legitimate, properly licensed customers, GERXDC has established a "Customer Authentication" policy (**Attachment 10**). This policy is summarized as follows: The GERXDC only services Giant Eagle Pharmacies which are owned by Giant Eagle, Inc. If, for any reason, a Giant Eagle Pharmacy is not licensed to receive Legend drug products or controlled substances, the GERXDC will no longer service the pharmacy.

GERXDC maintains copies of all customer licensure - state pharmacy licenses and DEA registration certificates. Licensing information will be verified through state agencies websites, as well as the DEA website (www.dea diversion.usdoj). If at any time a pharmacy is not licensed by the DEA and applicable State Board of Pharmacy, no Legend or controlled substances will be sold to them. GERXDC will report to the State Board of Pharmacy, DEA, and the FDA within three (3) business days if they are unable to authenticate a customer.

Suspicious Orders

GERXDC has developed an Order Monitoring System (OMS) to assist in detecting suspicious orders placed by any of their customers. The OMS algorithm generates flags based on monthly thresholds and ordering characteristics specific to the following:

- Pharmacy location
- Controlled Substance/Chemical
- Generic Product Indicator
- National Drug Code
- Week of the month
- Ordering patterns

Flagged controlled substance orders are generated through a daily report. The flagged orders cannot be filled until investigated and resolved by the OMS team, which includes designated individuals from Pharmacy Procurement, Pharmacy Operations, and the Loss Prevention Pharmacy Analyst. Pharmacy Procurement blocks the target drug from the identified pharmacy's order during the investigation. Pharmacy Procurement team members can utilize a

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computer software feature called Supplylogix Pinpoint Order or the drug management function of the pharmacy dispensing system to block the ability of a pharmacy to order the drug or chemical under investigation. GERXDC quarantines the product from the flagged store's order until the conclusion of the investigation. Orders for flagged stores are blocked through CSOS until investigated and resolved.

Investigations of flagged orders can include, but are not limited to the following:

- Purchasing patterns
- Dispensing patterns
- Percentage of controlled substance prescriptions
- Percentage of target controlled substances (e.g. Oxycodone, hydrocodone, buprenorphine)
- Form of payment (Third party or cash)
- Histories and patterns of prescribing physicians
- Interviews of store pharmacists and technicians
- Loss Prevention review of store surveillance video
- Review of Supplylogix Pinpoint Audit (used to identify pharmacies that are at risk for inventory built, I.e. purchases exceed dispensing)
- Review of Supplylogix Pinpoint Monitor (used to identify at risk purchasing patterns)

If the OMS team determines the flagged order is not suspicious, the orders are cleared for distribution by the GERXDC. If the order is deemed to be suspicious, the flagged item remains blocked, and the DEA is notified in writing within one business day of the determination. Law enforcement (DEA/State or local police) may also be notified.

Documentation of the above-described investigations will be retained in readily retrievable form for at least two years. A sample form used to document the investigation is attached to this report. The OMS policy and processes are reviewed quarterly (for effectiveness and quality) by the OMS Review Committee consisting of several individuals listed in the attached policy.

A NADDIS check revealed no derogatory information on these individuals.

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There is a pool of 45 additional employees who have access to the non-controlled pharmaceutical drugs contained in the pharmacy warehouse, located outside of the Schedule III through V controlled substance cage. These employees undergo the same background checks and have the same level of security as those individual who have access to the controlled substances. When the need arises, on a short term basis, such as an unscheduled illness, a temporary replacement employee maybe transferred from non-controlled drugs to controlled drugs.

9. DUE DILIGENCE

GIANT EAGLE RX DISTRIBUTION CENTER Manager Joshua DAUGHERTY advised the investigators that, unlike other drug distributorships, GIANT EAGLE RX DISTRIBUTION CENTER has only one customer, Giant Eagle Pharmacies. All orders for controlled substances are made via dedicated Giant Eagle pharmacy computer systems, whereby only pharmacists can place electronic orders for Schedule III through V controlled substances. DAUGHERTY advised that, at the store level, the pharmacist placing the order may not be the pharmacist on duty when the order is received. When orders are received at the pharmacy, it is the responsibility of a pharmacist and a pharmacy technician to enter controlled substances into the pharmacy inventory.

CHUNDERLIK advised investigators that GERXDC has developed an Order Monitoring System (OMS) to assist in detecting suspicious orders placed by any of their customers. The OMS algorithm generates flags based on monthly thresholds and specific ordering characteristics.

10. MEETING WITH MANAGEMENT

On August 1, 2017, Diversion Investigators Kupchick and Esquivel-Blatt meet with CHUNDERLIK to discuss the results of the audit. During this meeting, the investigators advised that both recordkeeping and security are in full compliance with the requirements set forth in Title 21 CFR.

11. VERIFICATIONS

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ARCOS records were utilized to verify purchases of controlled substances by GERXDC. No further action is required at this time.

This case is closed.

12. SPECIAL ASSIGNMENTS

No special assignments were completed.

INDEXING

1. GIANT EAGLE RX DISTRIBUTION CENTER
2500 Lovi Road, Freedom, PA 15042
DEA# RG0491047

* Subject of Cyclic Investigation on May 24, 2017 *

2. DOUGHERTY, Joshua

* Employed at GIANT EAGLE RX DISTRIBUTION CENTER; has access to controlled substances

3. TEYSSIER, Jacob

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* Employed at GIANT EAGLE RX DISTRIBUTION CENTER; has access to controlled substances

4. HUBERT, Mal [REDACTED]
[REDACTED]

* Employed at GIANT EAGLE RX DISTRIBUTION CENTER; has access to controlled substances

5. HUBSCH, David [REDACTED]
[REDACTED]

* Employed at GIANT EAGLE RX DISTRIBUTION CENTER; has access to controlled substances

6. PAPPAS, Sarah Brianna [REDACTED]
[REDACTED]

* Employed at GIANT EAGLE RX DISTRIBUTION CENTER; has access to controlled substances

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